Bard Peripheral Technologies
C.R. Bard, Inc.
13183 Harland Dr., N.E.
Covington, GA 30014

JAN - 5 2001

K003793

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENES INFORMATION

A. Submitter Information:

Submitter's Name: C.R. Bard, Inc., Peripheral Technologies Division
Submitter's Address: 13183 Harland Drive, Covington, GA 30014
Contact Person: Carol Vierling
Contact Person's Telephone Number: (770) 385-2347
Contact Person's FAX Number: (770) 385-2340
Date of Preparation: November 24, 2000

B. Device Name:

Bard® LUMINEXX™ Biliary Stent

C. Predicate Devices:

Bard® memotherm-FLEXX™ Biliary Stent
Cordis Biliary Stent

D. Device Description:

The Bard® LUMINEXX™ Biliary Stent and Delivery System is a stenting system designed to maintain the patency of biliary ducts obstructed by malignant neoplasms. The device includes the self-expanding Bard® LUMINEXX™ Biliary Stent pre-loaded on a unique delivery system. This 7 Fr delivery system is compatible with a 7 Fr introducer and accepts a .035" guidewire. The stent is available in various diameters and lengths. The delivery system is available in lengths of 80cm and 120cm.

K003793

E. Intended Use:

The Bard® LUMINEXX™ Biliary Stent is indicated for use in the treatment of biliary strictures resulting from malignant neoplasms.

F. Technological Characteristics Summary:

The Bard® LUMINEXX™ Biliary Stent is a metal mesh stent constructed of nitinol. Tantalum discs on each end of the stent provide enhanced radiopacity. The stent is self-expanding and is packaged pre-mounted on a disposable delivery system.

G. Performance Data:

The Bard® LUMINEXX™ Biliary Stent has increased radiopacity when compared to the Bard® memotherm-FLEXX™ Biliary Stent. Bench data indicate that the stent and delivery system are comparable to the Bard predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 5 2001

Ms. Carol Vierling
Manager, Regulatory Affairs
Bard Peripheral Technologies
C.R. Bard, Inc.
13183 Harland Dr., N.E.
COVINGTON GA 30014

Re: K003793
Bard® LUMINEXX™ Biliary Stent and Delivery System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: November 30, 2000
Received: December 8, 2000

Dear Ms. Vierling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003793

Device Name: Bard® LUMINEXX™ Biliary Stent and Delivery System

FDA's Statement of the Indications For Use for device:

The Bard® LUMINEXX™ Biliary Stent and Delivery System is indicated for use in the treatment of biliary strictures resulting from malignant neoplasms.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003793

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)